IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent application of:

Applicant(s):	Martin Brady et al.
Application No.:	10/753,979
Filed:	January 8, 2004
Title:	HOLLOW STYLET FOR INFUSION CATHETER SYSTEMS, DEVICES, AND METHOD
Examiner:	Laura C. Schell
Art Unit:	3767
Docket Number:	SCHWP0211USA

REPLY BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The undersigned submits this brief in reply to the Examiner's Answer. This reply brief is being timely submitted in view of the Office communication dated December 8, 2009, wherein the Examiner's Answer was amended and a new period for reply was set to January 8, 2010.

The Examiner's responses to appellants' arguments are discussed below in the order presented in the Examiner's Answer.

Claim 1

In response to appellants' position that it would not have been obvious to look to Thomas to cure the deficiency of Elsberry since Elsberry's purpose is to prevent coring of tissue, the Examiner stated:

> Elsberry was used as the primary reference because it had all of the structure claimed by Appellant except for the remotely detectable locator. The examiner brought Thomas in as a secondary reference because it teaches an obturator (equivalent to Appellant's claimed inner rigid tube used for guiding) which is inserted into a catheter and used to guide a catheter for placement, similar to Applicant's system, and more importantly because it teaches that the obturator has a radiopaque marker (band of radiopaque material) at its tip. The radiopaque material can be visualized radiographically, such as via fluoroscopy, to see where the tip of the obturator is within the patient's body in order to position the obturator and catheter in the correct position (abstract and col. 3, lines 10-18 of Thomas).

In view of this, the Examiner clearly is picking and choosing from the references certain features and then combining them in an effort to arrive at the subject matter of claim 1, to the total disregard of what each reference fairly teaches the skilled person. As explained in appellants' main brief, lacking is any reasonable basis for the combination advanced by the Examiner. The Examiner is doing nothing more than a hindsight reconfiguration of the base reference to arrive at the claimed subject matter.

The Examiner also takes issue with appellants' arguments respecting real time tracking in the context of the present invention. In appellants' main brief it was pointed out that claim 1 recites features relating to real time, or online, tracking versus offline or static position detection according to Thomas. In particular, the claimed system comprises, *inter alia*, a positioning system that can be coupled to an image-guided surgical workstation; and a remotely detectable locator on the hollow rigid tube trackable by the positioning system as the hollow rigid tube is tunneled through tissue in the patient's body toward the target location whereby the progress of the locator can be

tracked and thus the position of the hollow rigid tube can be positionally tracked by the positioning system for proper positioning of the infusion catheter in relation to the patient's body into which the hollow rigid tube and catheter have been inserted and displayed on a monitor of the image-guided surgical workstation. That is, the position of the remotely detectable locator is tracked as the rigid tube is tunneled through the tissue in the patient's body. Neither Elsberry nor Thomas offers any suggestion of this real time tracking.

The Examiner responds as follows:

> Appellant further argues that the combination of Elsberry and Thomas do not teach "real time tracking". The examiner would like to point out, however, that Appellant has not claimed "real time tracking" within the claim language. Appellant is arguing narrower details that what is actually being claimed. Appellant further argues that the claimed "image-guided surgical workstation" is known to one of ordinary skill in the art to be a system that provides real time tracking, however, Appellant's specification does not define the "image-guided surgical workstation" as needing to provide real time tracking. If one looks to Appellant's specification, Appellant only describes the image-guided surgical workstation in paragraphs 2 and 3 of page 6 and the first paragraph of page 7. No where in the specification is the image guided surgical workstation defined as a real time tracking system, and no where in the claims is there any requirement for real time tracking.

In view of the Examiner's comments, it is respectfully submitted that the skilled person would readily appreciate that claim 1 does involve real time tracking given appellants' specification. The Board's attention is invited to take judicial notice of the definition of "Image-guided surgery" in Wikipedia:

> Image-guided surgery is the general term used for any surgical procedure where the surgeon uses indirect visualization to operate, i.e., by employing imaging instruments in real time, such as fiber optic guides, internal video cameras, flexible or rigid endoscopes, ultrasonography, etc. Most image-guided surgical procedures are minimally invasive. (emphasis added)

In the case of claim 1, the system includes a remotely detectable locator on the hollow rigid tube trackable by the positioning system as the hollow rigid tube is tunneled through tissue in the patient's body toward the target location whereby the progress of the locator can be tracked and thus the position of the hollow rigid tube can be positionally tracked by the positioning system for proper positioning of the infusion catheter in relation to the patient's body into which the hollow rigid tube and catheter have been inserted and displayed on a monitor of the image-guided surgical workstation.

The Examiner also argues that tracking of Thomas' radiopaque marker via fluoroscopy (as Rosenman discloses) could be considered real time tracking. The Examiner correctly observes that fluoroscopy involves taking a radiographic image and that such an image can be used to determine if a device is in the correct position. In order to take such an image, the surgical procedure must be interrupted to allow the image to be taken. Otherwise the surgeon who is manipulating the catheter would be exposed to x-ray radiation and this is undesirable even if exposed once and much less to arrive at anything approximating real time tracking while the catheter is being tunneled through tissue in a patient's body.

Claim 2

The Examiner also takes issue with the comments in appellants' main brief regarding the effect of the hole 24 in Elsberry. The Examiner contends:

> With respect to Appellant's arguments regarding claim 2 and Elsberry's device not being able to hold fluid in the hollow tube, as is claimed, due to Elsberry's backfill hole 24, it is the examiner's position that the valve 12 of Elsberry is closed to retain what fluid is in the tube during insertion of the device. Just as a drinking straw has two open ends, when the straw is in a cup filled with liquid and some liquid is within the straw, when a person places a finger over one open end of the straw and lifts the straw out of the cup of liquid, the liquid that is within the straw does not flow out the open end. The finger over the open end of the straw (equivalent to Elsberry's valve 12) creates a vacuum within the device preventing fluid from exiting the other open hole in the straw (equivalent to Elsberry's hole 24). Therefore when valve 12 is closed, it will retain any fluid that is within the inner hollow tube. Also see Elsberry, col. 4, line 56 through col. 5, line 3.

The Examiner is correct about how a liquid will be held in a straw if one end of the straw is capped as by one's finger. The Examiner, however, is wrong with respect to the effect of the hole. Taking the straw example, if one were to punch a hole in the side of the straw, the liquid beneath the hole would flow out of the straw through the uncapped end.

Hence, fluid will flow from the aspirating stylet of Elsberry as soon as it is partially withdrawn from the catheter. This is why the backfill opening 24 is provided, to allow fluid to flow from the stylet to fill the space between the stylet and catheter.

Claim 11

In connection with claim 11, the Examiner raises the issue of real time tracking which is discussed above.

Claim 16

In regard to claim 16, the Examiner discusses the element 22 (sealing means) of Elsberry which allows a portion of the inner tube to seal snugly against the inner surface of the catheter.

> The examiner would further like to point out that Elsberry discloses that the when the device is filled with fluid prior to insertion in the patient, the device is filled such that it is an air-free column of fluid (col. 4, lines 60-65). Therefore there is no air present within the assembly. Once the assembly is tunneled into the patient, the inner tube is withdrawn from the catheter and the vacuum created between the catheter and the inner tube pulls the fluid from the inner tube so that it empties into the catheter. Since the assembly was filled such that it was "air-free", no air would pass between the two tubes despite the presence of hole 24.

The problem with this analysis is that once the seal (22) is broken, air can pass into the inner tube as is intended by Elsberry. Claim 16, however, recites "wherein at least a portion of an inner diameter of the flexible infusion catheter snugly seals to an outer diameter of the hollow tube to prevent air from passing therebetween as the hollow tube is withdrawn from the flexible infusion catheter" (emphasis added).

Claim 18

The above discussion regarding real time tracking addresses the Examiner's comments regarding claim 18.

Claims 7 and 15

With respect to Appellant's arguments regarding claims 7 and 15 and Maginot only showing a clamp for closing a catheter on itself, the Examiner states that "Maginot shows a clamp used for clamping tubing closed, and that clamping tubing of various durometers (plastic strengths) is well known in the art and that the addition of the Maginot reference to the rejection is to indicate this point and to show that adding a clamp to Appellant's system does not make Appellant's system novel or non-obvious." Claim 7, however, involves more than just adding a clamp. According to claim 7, the proximal end of the tubular catheter includes a clamp that closes around the hollow tube. This is not disclosed nor suggested by Maginot.

Claims 13 and 14

No further comments are deemed necessary.

Conclusion

In view of the foregoing and appellants' main brief, it is respectfully submitted that the claims are patentable over the applied art and that the rejections advanced by the Examiner should be reversed.

Respectfully submitted,

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/Don W. Bulson/

By :_____

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